



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
-----------------	-------------	----------------------	---------------------	------------------

10/502,239

07/22/2004

Heinrich Schubert

E7900.2001/P2001

4005

24998 7590 09/09/2008

DICKSTEIN SHAPIRO LLP
1825 EYE STREET NW
Washington, DC 20006-5403

EXAMINER

EREZO, DARWIN P

ART UNIT

PAPER NUMBER

3773

MAIL DATE

DELIVERY MODE

09/09/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/502,239	Applicant(s) SCHUBERT, HEINRICH	
	Examiner Darwin P. Erez	Art Unit 3773	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 June 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-22 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-22 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. This Office action is in response to the amendment filed on 6/6/08. The amendment has overcome the claim objections and the replacement Abstract is acceptable.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

4. Claims 1-9, 11, 14, 15 and 18-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 4,873,975 to Walsh et al. and in view of US 4,892,098 to Sauer.

Walsh discloses an anastomosis connector comprising an inner sleeve **12** mounted on an end of a first hollow organ such that the end can be everted over the inner sleeve (Figs. 9A-9B); and an outer sleeve **16** mounted around the end of a second hollow organ **84**, wherein the inner and outer sleeves are made of electrically conductive materials, such as stainless steel (col. 12, ll. 34-44), thus being capable of

being connected to an external current having a control means so that a current can be applied to the electrically conductive materials (the external current is not positively recited in the claims); wherein any surface of the sleeves would inherently be electrically conductive; wherein the outer sleeve is in the form of a wired loop; wherein the inner sleeve has a flange that acts as a fitting element against the outer sleeve; and wherein the sleeves are cylindrical. The connector of Walsh is viewed as being removable because the connector can be removed from a patient at any point in time, whether a blood vessel is resected along with the connector or even if the connector is removed from a dead patient. The device is also capable of being used as an electrocoagulative anastomosis connector because the device is made of stainless steel, which is an electrically conductive material, wherein the entire contact surface of the device would be electrically conductive to the construction of the connector; wherein the connector has smooth surfaces, as shown in Fig. 1.

Walsh discloses the outer sleeve having ends that are separable (pivotal) but is silent with regards to the inner sleeve being separable. However, it would have been obvious to one of ordinary skill in the art at the time the invention was made to make the inner sleeve be separable since it has been held that constructing a formerly integral structure in various elements involves only routine skill in the art. *In re Dulberg*, 289 F.2d 522, 523, 129 USPQ 348, 349 (CCPA 1961). It is noted that modifying the inner sleeve to have various elements will inherently provide pivotal portions and breaking sites.

Furthermore, Sauer discloses that anastomosis connectors are known to be formed in various elements (Figs. 4 and 5), which allows the connector to be opened and closed on the hollow body organs. Thus, modifying the device of Walsh to have a separable inner sleeve would allow the sleeve to mount on the outside of the first hollow organ prior to the step of everting the end of the tissue over the sleeve.

It also would have been obvious to provide interlocking fastening means between the separated portions of the sleeve in order to maintain the assembled shape. The examiner takes Official notice that interlocking fastening means such as male and female connectors are well known in the art connecting one portion to another portion.

5. Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over Walsh et al. and Sauer, as applied to the rejections above, and in further view of US 4,470,415 to Wozniak.

The above combination of Walsh and Sauer discloses all the limitations of the claim except for portions of the inner and outer sleeves to be formed of a plastic material. However, the patent to Wozniak discloses that anastomotic connectors are known to be formed from plastic materials. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the device of Walsh/Sauer to have all or portions of the inner and outer sleeves to be made of plastics since plastic, as well as stainless steel, are well known biocompatible materials used to formed medical implants.

6. Claims 12, 13, 16, 17 and 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Walsh et al. and Sauer, as applied to the rejections above, and in further view of US 5,649,937 to Bito et al.

The above combination of Walsh and Sauer discloses all the limitations of the claim except for the device having a sensor for measuring the impedance or temperature of the device, or wherein the device is connected to a current source. However, the use of current to enhance an anastomotic site is well known in the art, as disclosed by Bito. Bito discloses an anastomotic device having sensors **26** for providing various parameters for the device, and wherein a current is provided to anastomotic connector for electrocoagulation of the tissues. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to use modify the device of Walsh/Sauer to include sensors and be connected to an electric current because providing an electric current to an anastomotic connector will enhance the integrity of the seal between the first and second hollow organs via electrocoagulation. Furthermore, the device of Bito is usable with the device of Walsh because Walsh discloses a device that is made of electrically conductive materials.

Response to Arguments

7. Applicant's arguments filed 6/6/08 have been fully considered but they are not persuasive.

The applicant's main argument is directed towards the newly added limitation of a "removable electrocoagulative anastomosis device". It was argued that the connector of Walsh is retained in the patient's body and is not removed. However, the limitation merely states that the device is capable of being removed. As explained in the rejections above, there are various situations in which the connector of Walsh can be removed. Furthermore, the recited limitation above has not been given patentable weight because the recitation occurs in the preamble. A preamble is generally not accorded any patentable weight where it merely recites the purpose of a process or the intended use of a structure, and where the body of the claim does not depend on the preamble for completeness but, instead, the process steps or structural limitations are able to stand alone. See *In re Hirao*, 535 F.2d 67, 190 USPQ 15 (CCPA 1976) and *Kropa v. Robie*, 187 F.2d 150, 152, 88 USPQ 478, 481 (CCPA 1951).

It was also argued that the Sauer reference does not cure the deficiencies of Walsh. However, this is not persuasive as the Sauer reference was merely provided to show that anastomosis are known in the art to be formed from separate elements. Furthermore, the courts have held that constructing a formerly integral structure in various elements involves only routine skill in the art. *In re Dulberg*, 289 F.2d 522, 523, 129 USPQ 348, 349 (CCPA 1961).

Conclusion

8. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Darwin P. Erezzo whose telephone number is (571)272-4695. The examiner can normally be reached on M-F (8:00-4:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jackie Ho can be reached on (571) 272-4696. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Darwin P. Erezon/
Primary Examiner, Art Unit 3773